REMARKS

This Amendment is made in response to the Final Action mailed May 26, 2010. Claims 19-34 have been cancelled. Claims 1-18 remain pending in this patent application. Entry of the remarks herein and reconsideration and withdrawal of the objections to and rejections of the application are respectfully requested in view of the following remarks.

Claims 1-18 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Action alleges that the data provided by Applicants in support of their "preventing plaque", "preventing plaque build-up" and "preventing gingivitis" claims does not meet the enablement requirement. In particular, the Action states that there are numerous variables that could have accounted for the data provided, for example, differences between the control and test groups in diet, brushing habits and bioactivity in the mouth, all could reasonably account for the differences in the data between the groups. Applicants respectfully disagree. Reconsideration and withdrawal of the rejection are respectfully requested.

As can be seen in the description of Example 2 (at paragraphs [0070] through [0075] of published application US 2007/0264291 A1), the study was a randomized, double-blinded, well controlled clinical trial, the protocol for which was reviewed by the Ethical Committee of the Wuhan University, School of Stomatology, Wuhan Province, China. Indeed, the clinical trial results are published in the Journal of Clinical Periodontology, Vol. 33:86-91 (2006) (copy enclosed), a highly reputable, peer reviewed periodontal research journal. Applicants submit that this level of scrutiny certainly demonstrates that the clinical study was well designed to demonstrate the desired endpoints, as well as addressing the variables associated with such a study.

In the Methods and Materials section of the enclosed journal article, a detailed description of the clinical trial clearly shows that the variables of concern in the Action were well controlled. For example, participants were instructed on brushing technique and given a diary to record their brushing habits: "After prophylaxis, all patients were instructed on the proper brushing technique and were given either the test dentifrice (non-aqueous toothpaste containing 5% NovaMin) or a placebo formulation (non-aqueous toothpaste without NovaMin) along with a diary to record product usage and daily oral hygiene activities". The toothbrush variable was addressed by supplying all participants with the same toothbrush: "Subjects were also given a soft bristled toothbrush to use during the clinical study". In addition, participants were instructed to "refrain from all other unassigned forms of oral hygiene, including non-study toothbrushes or toothpastes, dental floss, chewing gum or oral rinses during the study", thereby minimizing behavior that may have

influenced the results. After the study was completed, the participants' diaries were collected and reviewed by the study director, who found no violations of the study protocol.

Applicants urge that the data generated in Example 2 of the instant application, are a result of a well controlled study that addressed the variables found in such studies. Therefore, the data generated would enable one of skill in the art to conclude, as did Applicants, that the non-aqueous composition is useful for preventing plaque or plaque build-up and for preventing gingivitis. Favorable reconsideration of the rejection under Section 112, first paragraph, is requested.

Claims 1-18 have been rejected under 35 USC §103(a), as being unpatentable over U.S. Patent 5,882,360, granted March 16, 1999, to Gates et al. ("Gates") in view of International Application No. WO 99/13852, published March 25, 1999, in the name of Litkowski et al. ("Litkowski"). According to the Action, Gates teaches a dentifrice containing dentally acceptable abrasives, specifically listing silica, plastic particles, alumina, calcium carbonate, and calcium pyrophosphate as suitable abrasives. Further, the Action states that Litkowski teaches the incorporation of abrasives such as silica, plastic particles, alumina, calcium carbonate and calcium pyrophosphate; and that the bioactive glass can replace all, some, or none of the abrasives (see, for example, page 4, lines 21-29). Based on these disclosures, the Action concludes that it would have been obvious to modify the composition of Gates to include the bioactive glass of Litkowski based on its recognized suitability for its intended use as both a whitening agent and as an abrasive. Reconsideration and withdrawal of the rejection are respectfully requested.

Applicants submit that the invention herein is directed to a **method** for preventing or reducing plaque or plaque build-up and a **method** for preventing or reducing gingivitis. Neither Gates nor Litkowski teach or suggest such methods.

Gates teaches an anhydrous composition containing an abrasive but does not teach the use of bioactive glass as an abrasive or the use of bioactive glass for the prevention or reduction of plaque, plaque build-up and gingivitis. The Examples of Gates all contain silica as the abrasive component. Litkowski teaches a composition for whitening teeth, which composition contains a bioactive glass and potentially an abrasive; especially preferred is silica (see, page 4, line 25). Gates' compositions already contain the preferred abrasive of Litkowski, that is, silica. Applicants submit that one of skill in the art would not have been motivated by the teaching in Litkowski to modify the composition of Gates by using an alternative abrasive since Gates was already using the preferred abrasive taught by Litkowski, silica.

At best, assuming *arguendo* that one of skill in the art was to have substituted silica with a bioactive glass in Gates' composition, the expectation would be that the composition

would whiten teeth. There would have been no expectation that the composition was effective for the prevention or reduction of plaque, plaque build-up and gingivitis.

Nonetheless, in further support of the obviousness argument, the Action asserts that the use of bioactive glass for the prevention of dental caries and/or gingivitis was known in the art at the time of the invention (as taught by U.S. Patent 6,190,543, granted February 20, 2001, to Stoor et al. ("Stoor")). However, Applicants urge that Stoor teaches an **aqueous** composition containing preferably 40-80 weight percent of bioactive glass (see, column 3, lines 4-7) for achieving its use. Effectively, this is a teaching away of the instant invention. In contrast to Stoor, this invention relates to a method for the prevention or reduction of plaque, plaque build-up and gingivitis by contacting all or a portion of the individual's oral cavity with a **non-aqueous** composition comprising a carboxyvinyl polymer, a humectant, a polyethylene glycol and about **0.25 to about 10% by weight bioactive glass** particles having an average particle size of less than 20 microns for a time effective to prevent or reduce plaque or plaque build-up. Stoor, as a secondary teaching, does not remedy the deficiencies of the primary combination of documents.

Based upon all of the above distinctions, Applicants urge that Gates and Litkowski, read alone, or in any fair combination, fail to teach or suggest the instant invention. A *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the Section 103 rejection are respectfully requested.

In view of the above remarks, reconsideration of claims 5-9 and allowance of this application are earnestly solicited.

Respectfully submitted,

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